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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/001,407	10/22/2001	Yeasing Y. Yang	GP117-03.UT	3070

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GEN PROBE INCORPORATED  
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EXAMINER

PARKIN, JEFFREY S

ART UNIT PAPER NUMBER

1648

DATE MAILED: 03/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/001,407	<b>Applicant(s)</b> YANG ET AL.	
	<b>Examiner</b> Jeffrey S. Parkin, Ph.D.	<b>Art Unit</b> 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 03 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 09 January 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 55-90 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 55-90 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>02202003; 02122002</u> . | 6) <input type="checkbox"/> Other: _____  |

Serial No.: 10/001,407

Applicants: Yang, Y. Y., and T. A. Burrell

Docket No.: GP117-03.UT

Filing Date: 10/22/01

### **Detailed Office Action**

#### ***Status of the Claims***

Acknowledgement is hereby made of receipt and entry of the communication filed 09 January, 2004, wherein Group V (claims 55 and 56) was elected without traverse. Claims 1-54 were canceled and new claims 57-90 introduced in the response. Claims 55-90 are pending in the instant application.

#### **37 C.F.R. § 1.821-1.825**

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 C.F.R. § 1.821 through 1.825 for the reason(s) set forth below or on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. **Perusal of the paper copy of the sequence listing revealed that page 4 (which includes SEQ ID NOS.: 18-26) is missing from the sequence listing.** Applicants are required to submit a duplicate copy of the sequence listing containing the requisite information pursuant to the requirements set forth above.

#### **37 C.F.R. § 1.98**

The information disclosure statement filed 20 February, 2003, has been placed in the application file and the information referred to therein has been considered. The information disclosure statement filed 12 February, 2003, fails to comply with 37 C.F.R. § 1.98(a)(2), which requires a legible copy of

each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

**35 U.S.C. § 112, Second Paragraph**

Claims 55-90 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are directed toward kits for detecting HIV-2 nucleic acids that comprise primers and probes. However, none of the structural components of the kit are clearly set forth. Moreover, instructions/directions on how to employ the kit were also not set forth. Appropriate correction is required (i.e., A kit for detecting human immunodeficiency virus type 2 (HIV-2) nucleic acids comprising the following: a) a container/vial comprising a first primer ...; b) a container/vial comprising a second primer ...; c) a container/vial comprising an oligonucleotide probe ...; and instructions for employing/using said kit to detect HIV-2 nucleic acids corresponding to the LTR).

**35 U.S.C. § 103(a)**

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the

art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. § 103(c) and potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103(a).

Claims 55-90 are rejected under 35 U.S.C. § 103(a) as being unpatentable over the combined teachings of Pieniazek *et al.* (1991), Myers *et al.* (1993), Nelson *et al.* (1997), and Sorge *et al.* (2000). The claims are directed toward kits for the detection of HIV-2 nucleic acids comprising various primers and probes derived from the HIV-2 long terminal repeat (LTR), or alternatively, the T7 promoter region. Additional claims are directed toward art-recognized modifications of the claimed primers/probes.

Pieniazek *et al.* (1991) describe polymerase chain reaction assays (PCR) employing independent primers/probes sets used for the amplification and detection of the HIV-1/-2 LTR. This teaching does not disclose a kit comprising the specific

sequences claimed by applicants (i.e., SEQ ID NOS.: 1 or 9).

Myers et al. (1993) provide the complete nucleotide sequences of numerous HIV-2 LTRs. This teaching also fails to disclose the precise primers currently being claimed.

Sorge et al. (2000) provide various primers and probes including T7-based primers.

Finally, Nelson and colleagues (1997) provide various chemical modifications to primers/probes that make them more effective for the detection of nucleic acids. This teaching clearly discloses all of the art-recognized modifications currently being claimed.

The prior art can be summarized as follows:

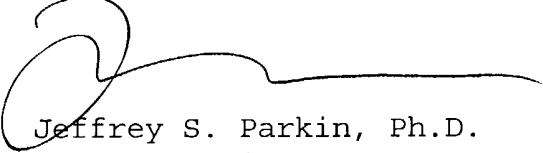
- 1) The LTR nucleotide sequences of numerous HIV-2 isolates were well-known and publicly available.
- 2) HIV-2 nucleic acid detection assays employing HIV-2 LTR-specific primers and probes were well-known.
- 3) Primers and probes obtained from the T7 promoter region were commonly employed.
- 4) Various chemical modifications of oligonucleotide primers/probes were well-known and routinely performed to facilitate the detection of nucleic acids.

Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to prepare HIV-2 LTR-specific primers and probes, as well as T7-based primers and probes, to detect HIV-2 nucleic acids in an enzymatic assay. One of ordinary skill in the art would have been motivated to include such primers and probes in a kit to facilitate the rapid and facile detection of HIV-2. Absent evidence to the contrary, the identification and selection of suitable primer pairs and probes was routine and well within the purview of one of ordinary skill in the art.

**Correspondence**

Any inquiry concerning this communication should be directed to Jeffrey S. Parkin, Ph.D., whose telephone number is (571) 272-0908. The examiner can normally be reached Monday through Thursday from 9:30 AM to 7:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner are unsuccessful, the examiner's supervisors, Laurie Scheiner or James Housel, can be reached at (571) 272-0910 or (571) 272-0902, respectively. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (571) 272-1600.

Respectfully,



Jeffrey S. Parkin, Ph.D.  
Patent Examiner  
Art Unit 1648

21 March, 2004